



MULTICAREIN



USER'S MANUAL

**MULTIPARAMETER DIAGNOSTIC
DEVICE**





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INTRODUCTION

THE MULTICAREIN SYSTEM

Thank you for choosing MULTICAREIN system. MULTICAREIN is a new system, suitable for the monitoring of glucose, cholesterol and triglycerides in the blood*.

MULTICAREIN uses two different technologies:

- Amperometric, with MULTICAREIN glucose strips.
- Reflectometric, with MULTICAREIN cholesterol and triglycerides strips.

Self-testing of glucose, cholesterol and triglycerides could be helpful, but any treatment has to be anyway agreed with the physician.

*CAUTION	<i>The system is calibrated for the use of capillary blood; for the use of venous blood (only possible with cholesterol and triglycerides strips) contact the Customer Service for the correct calibration.</i>
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INFORMATIONS ABOUT MULTICAREIN SYSTEM LINE

The MULTICAREIN system line includes:

- MULTICAREIN device
- MULTICAREIN strips
- Autolancet
- MULTICAREIN control solutions
- MULTICAREIN data manager software
- MULTICAREIN mobile app. and cloud (only for bluetooth MULTICAREIN**)

Read carefully the instructions for use of the MULTICAREIN strips that you are using and read the instructions for use of the autolancet device contained in the MULTICAREIN meter box.

**Bluetooth represents an optional



THE DEVICE

FRONT



1. Display: shows test results, error messages and results stored in memory.
2. Power button, press this button to:
 - a. switch-on or switch-off the device;
 - b. enter the SETTINGS (SET) when the device is on;
 - c. confirm the SETTINGS.
3. "+" button, press this button to:
 - a. enter the MEMORY of the device;
 - b. recall results stored in the MEMORY of the device;
 - c. change parameters and values while setting.
4. "-" button, press this button to:
 - a. enter the MEMORY of the device;
 - b. recall results stored in the MEMORY of the device;
 - c. change parameters and values while setting;
 - d. delete the test results.
5. Test strip slot: insert the test strip here. When the test strip is inserted, the device will turn on automatically.
6. PC connector:
 - a. Connector to transfer data from the device to a computer.
 - b. Connection with Biosys device.
7. Cover: open this part for cleaning the optical window.

BACK



8. Battery housing: sliding cover for batteries replacement.
9. Data-chip slot: insert the data-chip here.
10. Strip ejector: slide it to dispose of the used strip.

THE DISPLAY



1		Data-chip symbol.
2	AVG	Average results symbol
3	MEM	Memory mode symbol
4	SET	Settings mode symbol
5		Low battery warning
6	888	Result or error messages
7	mmol/L mg/dL	Unit of measurement
8		Test analytes
9		Temperature symbol
10	20:00 am	Time
11		Acoustic alarm
12	20000	Date (month, day and year)

THE MEASUREMENT

When you switch on the device check always that the date (month, day and year) and time are correctly set to obtain accurate results (see page 18).

INSERTION OF THE DATA-CHIP

The MULTICAREIN device uses a data-chip which is contained in the strips box.

It is necessary to change the data-chip in the following situations:

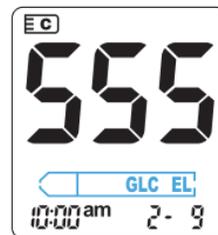
- a. When you want to change analyte.
- b. Before using a new strips box.

How to insert the data-chip

1. Remove the data-chip from the strips box.
2. Insert the data-chip in the slot placed on the lateral side of the device.
3. Gently press the data-chip up to the complete insertion.



- Press the power button and check if the code shown on the display matches the one printed on the label vial of the strips.
- If the data-chip is not inserted, it is not possible to perform the measurement.



- Analytes:



HOW TO OBTAIN A DROP OF BLOOD

To perform a measurement with MULTICAREIN system, it is necessary to collect a drop of capillary blood according to the following procedure:

1. Wash the hands with soap and hot water to increase the blood flow at the fingertips to ease the blood collection. Dry well the hands and check that the finger to be pricked is completely dried. Do not apply disinfectant or beauty cream before the finger pricking.
2. Prepare the autolancet that is contained inside the MULTICAREIN box meter.

Instruction for USE:



1. Twist and pull off the protective cap.
Discard the protective cap into the waste container.
2. Press the lancet against the sampling site.
3. Dispose of the used lancet into the waste container.



APPLICATION OF THE BLOOD

Read carefully the instructions for use of the strips that you want to use to perform the measurement.



1. Press the power button after inserting the data-chip. The code of the data-chip that appears on the display has to match the one printed on the strips vial. If it doesn't match please contact the Customer Service.
2. Wash your hands and dry them thoroughly.
3. Take out a strip from the vial and insert it in the device, with the printed or coloured part facing up. You will hear a click and the device will emit an acoustic signal ("beep").

PROCEDURE TO TEST GLUCOSE



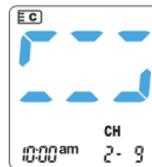
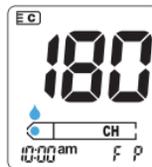
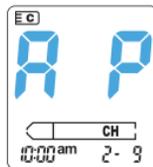
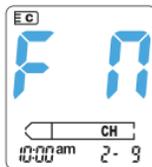
- 3a.** Perform the finger pricking with the autolancet.
Apply a drop of blood on the side of the strip that comes out of the device. Let the strip aspirate the blood until to see the moving segments on the display and you will hear an acoustic signal ("beep").

If the blood volume is not enough the measurement does not start.

PROCEDURE TO TEST CHOLESTEROL



- 3.b.1.** Sit down for one minute with the arm along the body. Massage the finger to be pricked to increase the blood flow. After inserting the strip, for cholesterol test, "F" (female) on the left and "M" (male) on the right will appear on the display. Press the corresponding button "-" or "+" to select the gender. After about two seconds, "A" (before meal) on the left and "P" (after meal) on the right will appear on the display. Press the corresponding button "-" or "+" to select the nutritional state. The selected letter will be shown for two seconds on the display. After that, the blinking drop will appear on the display, indicating that the meter is ready to receive the blood. Execute the puncture of the finger by the autolancet. Remove the first drop with a sterile gauze and gently press the finger to obtain the second drop. Apply the blood on the white circular area of the strip coming out from the meter. Wait until moving segments will appear on the display and until to hear an acoustic signal ("beep").



PROCEDURE TO TEST TRIGLYCERIDES



- 3.b.2.** Sit down for one minute with the arm along the body. Massage the finger to be pricked to increase the blood flow. After inserting the strip, the code of the data-chip and the blinking drop will appear on the display, indicating that the meter is ready to receive the blood. Perform the finger pricking by using the autolancet. Remove the first drop with a sterile gauze and gently press the finger to obtain the second drop. Apply the blood on the white circular area of the strip coming out from the meter. Wait until moving segments will appear on the display and until to hear an acoustic signal (“beep”).
- 4.** Wait for the result, which will be displayed and stored in the memory of the device automatically (refer to the instructions for use of the strips that you are using to know the reading time).
- 5.** Use the ejector on the back side of the device to remove the used strip, pointing the device down.

WARNINGS

If you get results which do not correspond to your feelings, run a check of the MULTICAREIN device and contact your physician. If you get extreme results, too high (Hi) or too low (Lo), contact your physician immediately.

When the measurement is finished, it is possible to switch off the MULTICAREIN device. The device will switch off automatically after 60 seconds if it is not used for other operations.

The last measured value, along with date and time, will be saved in position 1 in the memory of the device. The values previously measured will be saved in position 2, 3 etc. starting from the most recent. How to recall from the memory a measured value and how to erase memorized values is described on page 17.

The used strips and materials have to be properly disposed, avoiding contamination. The device has to be disposed following the electric and electronic waste law.



In laboratories and hospitals, the procedures of biological safety must be followed when handling potentially infected material, in particular when measurements are performed on different patients.

To avoid infections, clean the device regularly and dispose of the used strips in a way that there is no risk of infections for other people.

THE STRIPS

MULTICAREIN STRIPS

The correct use of **MULTICAREIN** strips is very important to obtain accurate results.

Therefore it is important to keep in mind the following points:

- The strips are sensitive to light and humidity, store them only in their original vial.
- Keep the vial away from direct sunlight. Store it at temperatures between 5-30°C (41-86°F).
- Use the strip immediately after removing from the vial and close the vial immediately with its cap.
- The strips must not be used after the expiry date.
- Write down the date of the first opening on the vial: the strips must be used within 90 days after the vial has been opened.
- Do not use damaged strips.
- Read carefully the instructions for use contained in the strips box.
- Perform measurements only with original **MULTICAREIN** strips.
- For using venous blood with cholesterol and triglycerides strips, please contact the Customer Service.





CONTROL SOLUTIONS

MULTICAREIN CONTROL SOLUTIONS

Read carefully the instructions for use of the control solutions that you are using.

It is possible to check the proper working of **MULTICAREIN** device by using the **MULTICAREIN** control solutions. The control solutions can be purchased as a separate accessory through specialized retailers. The control solution is applied on the strips just like blood. When the test is performed with the control solutions, the result must fall within the range printed on the strips vial label that you are using. Write down the date of the first opening on the vial of the control solution. The control solutions must be used within 90 days from the first opening. Do not use control solutions after the expiration date.

You should perform a control solutions test when:

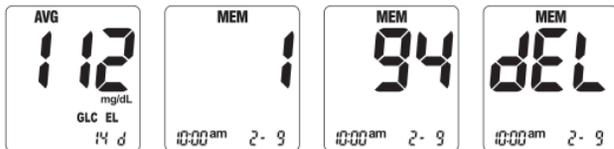
- Suspecting a possible defect of the **MULTICAREIN** device.
- Suspecting the possibility of a malfunction or wrong measurement.

The result obtained with the control solutions must be deleted by the memory of the device in order to not interfere with the average calculation of the results, in particular with the average of the glycemia.

MEMORY FUNCTIONS

The MULTICAREIN device stores up to 500 test results for all analytes, letting you review them from the most recent 1 to the oldest 500.

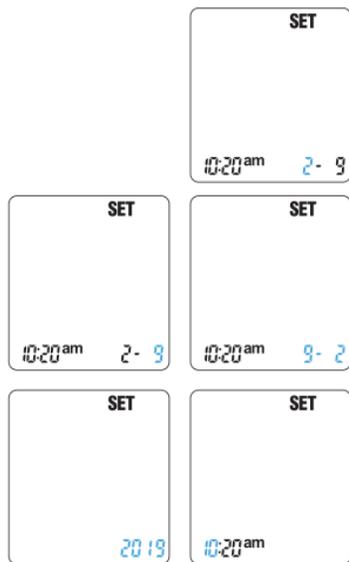
To recall memory data it is necessary to insert the data-chip of the analyte you want to recall the memories.



1. After turning on the device press and release the button “-” or “+”, the device will enter the MEMORY and the average of the results (AVG) will be displayed.
2. Hold on the button “+” the number 1 will be displayed which refers to the most recent result. When you release the button, the stored result will be displayed.
3. Pressing again the button “+”, the number 2 will be displayed.
4. Press the button “-” together with the power button for half second to delete a single stored result; after deleting a single result “deL” will be displayed.
5. Press the button “-” together with the power button for 5 seconds to delete all results stored in memory; After deleting all results “Clr” will be displayed.

GENERAL SETTINGS

CHANGING THE SETTINGS



1. With the device on, press the power button for 3 seconds to enter the setting (SET).
2. Press and release the "-" or "+" button until reaching the correct month. Confirm the setting by pressing and releasing the power button.
3. Press and release the "-" or "+" button until reaching the correct day. Confirm the setting by pressing and releasing the power button.
4. Press and release the "-" or "+" button to modify the date format (mm-dd) or (dd-mm). Confirm the wanted format by pressing and releasing the power button.
5. Press and release the "-" or "+" button to modify the year, until reaching the correct year. Confirm the setting by pressing and releasing the power button.
6. Press and release the "-" or "+" button until reaching the correct hour. Confirm the setting by pressing and releasing the power button.

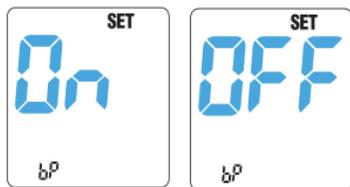


7. Press and release the "-" or "+" button until reaching correct minutes. Confirm the setting by pressing and releasing the power button.
8. Press and release the "-" or "+" button to modify the time format 12h or 24h. Confirm the wanted format pressing and releasing the power button.
9. Press and release the "-" or "+" button to modify the unit of measurement, mg/dL or mmol/L. Confirm the wanted unit of measurement by pressing and releasing the power button.
10. Press and release the "-" or "+" button to modify the number of days you want the average of results (0,7,14,21,28 days - "0" means that the device will not show any average when recalling the memories. Confirm the setting by pressing and releasing the power button.

IMPORTANT

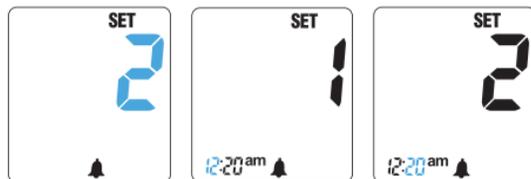
When replacing the batteries, the setting of the device will end with step 10 described above. Otherwise the setting of the device will continue with the following steps.

SETTING THE ACOUSTIC SIGNAL



11. Press and release the "-" or "+" button to enable or disable the acoustic signal. Confirm the setting by pressing and releasing the power button.

SETTING THE ALARMS



12. Press and release the "-" or "+" button to select first the hour and then the minutes of the first alarm. It is possible to set 4 alarms. The alarms are not activated if they are all set on 12.00am or 0.00.

ENABLING DATA TRANSFER TO A COMPUTER



All test results stored in MULTICAREIN device can be downloaded to a computer.

1. Install the software according to the manufacturer's instructions.
2. Connect the device to a computer by means of the cable.
3. Press and release the power button. The message "PC" will appear on the display.
4. Set up your computer software to receive information from the meter. After the data has been transferred, it is possible to switch OFF the device by pressing the power button and remove the cable.

If you have a bluetooth MULTICAREIN , you can use a dedicated application to share and manage the data.

MAINTENANCE AND STORAGE CONDITIONS

CARE AND MAINTENANCE



For glucose measurement it is not necessary a particular cleaning procedure, only if blood or other material (debris, dust, etc..) come into direct contact with the plastic support of the device. If so, wipe the device surface with a soft cloth dampened with 70% alcohol solution.



For cholesterol and triglycerides measurement the device uses an optical measuring method, thereby its components must be kept clean. To clean the optical components, lift the frontal cover and wipe the glass surface of the optic window with a soft cloth dampened with water. After cleaning, dry the optic of the device, avoiding scratching.

To perform measurements on different people, like for example in a hospital, clean the device after each measurement with a 70% alcohol solution before proceeding with the next measurement.

STORAGE AND MEASURING CONDITIONS

In order to get accurate results the measurement with MULTICAREIN strips has to be performed between 10-40°C (50-104°F). The MULTICAREIN kit (device and strips) must be stored at temperatures between 5°C (41°F) and 30°C (86°F).

WARNINGS

If the device is too cold or too hot for example after being stored in a car at very low or high temperatures, let it to cool down or to heat up slowly at room temperature for about 20 minutes.

ERROR MESSAGES

DISPLAY



E01
10:20 am 2-18

The measurement was carried out at a temperature out of the correct range.

Place the device in an area with temperature between 10°-40°C (50°-104°F) and wait until the device reaches the room temperature before performing the measurement.



E02
10:20 am 2-18

The strip is used or the reactive area is colored.

Use a new strip to perform the measurement.

The strip is not inserted correctly.

Insert again the strip; please make sure that the strip does not remain lifted up with respect to its support.

The blood was applied on the strip before waiting for the drop blinking on the display.

Take a new strip, insert it in the device, and apply the blood only after the blinking drop is displayed.

The optical window is dirty.

Open the plastic cover and clean the optical window without using soap or solvents.



E03
10:20 am 2-18

The strip has been removed from the device without applying the drop of blood.

Switch off the device with the power button. Insert again the strip and apply the blood without removing the strip from the device.

DISPLAY

E04

10:20am 2-18

PROBLEMS

The strip that you are using does not correspond to the analyte of the data-chip.

Wrong data-chip.

SOLUTIONS

Remove the data-chip and use the one corresponding to the strips that you are using and check whether the parameter symbol is the right one.

Remove the wrong data-chip and insert the correct one making sure that it corresponds to the test that you are performing.

E05

10:20am 2-18

Wrong reading of the data-chip or data-chip error.

Remove and insert again the data-chip. If the problem persists contact the MULTICAREIN Customer Service.

E06

10:20am 2-18

The blood volume is not enough.

Repeat the test with a new strip and apply a higher volume of blood.

E07

10:20am 2-18

The data-chip is not inserted.

Insert the data-chip corresponding to the strips that you want to use.

DISPLAY

PROBLEMS

SOLUTIONS



The result is lower than the lower limit of reading of that parameter (see also instructions for use of the strips).

If the result does not correspond to the personal sensations repeat the test. If "Lo" symbol appears again, contact your physician for additional informations.



The result is higher than the upper limit of reading of that parameter (see also instructions for use of the strips).

Contact immediately your physician and repeat the test in the hospital.



Result with battery symbol.

Batteries are draining; please get new batteries.



Blinking battery symbol.

Replace the batteries to perform the test (see page 27).



Blinking result.

Check the expiry date of the strips and repeat the test with new strips. The blinking result will not be stored in the memory.

REPLACING THE BATTERIES

MULTICAREIN device needs two 3V lithium batteries (type CR2032). If the battery icon is blinking, the charge is low and the batteries must be replaced before taking measurement.

Always insert new batteries and not used ones. Switch off the device before removing the batteries. Check whether the new batteries are the right ones.

How to replace batteries:

1. Let the battery housing slide out by pressing on the arrow printed on the battery compartment.
2. Remove the batteries from the plastic holder.
3. Place the new batteries with the negative side facing up.

Insert the cover of battery compartment and close it.

Dispose of used batteries according to local regulations.



WARNINGS

If batteries are replaced or simply removed for more than 60 seconds, it is necessary to set time and date again.



WARRANTY

INFORMATIONS OF WARRANTY CONDITIONS

Biochemical Systems International S.p.A. grants to the customer that the device **MULTICAREIN** will be free of material defects and manufacturer handling for 3 years starting from the purchasing date. During such period **Biochemical Systems International S.p.A.** should replace the defected device with an equivalent version or the same model after verifying the defect. Such warranty is subject to exceptions and limitations as described below. The warranty is limited to the replacement due to defects in some parts handling. Devices that present defects due to damages caused from improper use, alteration, negligence, technical assistance performed by not authorized personnel, accident, abuse or by using strips which are different from **MULTICAREIN** will not be replaced.

Biochemical Systems International S.p.A. reserves the right to apply technical modifications to the device **MULTICAREIN** without the obligation to insert such specifications to those products already introduced in the market. Any other warranty will be guaranteed for this product unless the replacement option described above. Every responsibility for special, indirect or consequential damages is excluded.

In order to provide you with future information and optimal service, please send us the registration card situated on the next page, duly completed at Biochemical Systems International. It is possible to register your device on the web: www.biosys.it, or throughs e-mail: info@biosys.it

WARRANTY CARD

Name: Surname:

Address:

City: Zip code:

Telephone: E-mail:

Serial No. (Meter back):

Date of purchase:

In accordance with D.L.gs.196 / 2003 on the protection of personal data, Biochemical Systems International S.p.A. would like to inform you that all the information you want to provide us will be treated in order to send you the requested material and processed electronically with the adoption of appropriate measures to guarantee safety.

AGREE

NOT AGREE

Date

Signature

Ship to: **BIOCHEMICAL SYSTEMS INTERNATIONAL S.p.A.**
Loc. Palazzo del Pero, 23 - 52100 Arezzo (AR) - ITALY



TECHNICAL FEATURES

Range of measurement	10-600 mg/dL (0.6-33.3 mmol/L) glucose. 130-400 mg/dL (3.3-10.2 mmol/L) cholesterol. 50-500 mg/dL (0.56-5.6 mmol/L) triglycerides.
Batteries	2x3V lithium batteries, type CR2032. The batteries can be used for approx. 1 year with 3 measurements per day (approx. 1000 measurements).
Dimensions/Weight	97 mm length; 49 mm width; 20,5 mm height/65gr (including batteries).
Display	LCD display.
Temperature limits	From 10°C to 40°C (from 50°F to 104°F).
Humidity limits	From 0% to 90% relative humidity (non condensing).
Memory capacity	500 measurements with date and time.
Interface for data processing	Connecting cable.
Special requirements for electromagnetic radiation	CE mark on the device indicates that it complies with the requirements of the CE directives 89/336/EEC relating to electromagnetic compatibility and 73/23/EEC.
Hints for Healthcare Professionals	The accuracy of the device should be checked after 3 years.
Waste management disposal when the device is unusable	Please refer to local updated regulations.

SYMBOLS



Number of pieces



Do not reuse



Recyclable



Direct current



Manufacturer



CE mark



Expiry date



Date of
manufacture



Read instruction
for use



Lot
number



In-Vitro
Diagnosticum



Serial
number



Catalogue
number



Keep away
from
sunlight



Store at
temperatures
between ...



Caution!
Follow
instructions



Do not dispose the device in the urban waste. Perform a separated collecting specific for electric and electronic waste. Please refer to local updated regulation.



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